REMARKS

I. Overview.

With this Response, the Applicant has amended portions of the Specification to overcome the Examiner's objections under Section 112; has amended several of the claims to overcome the Examiner's objections thereto under Section 112; and has amended some of the claims to more particularly point out those distinctions between the Applicant's invention and the art of record.

Additionally, the Applicant discusses the prior art, and sets forth arguments describing why the present invention is patentably distinguishable from the art of record, and why therefore the Claims should be allowed.

II. Rejections under Section 112

In the Official Action, the Examiner rejected Claims 6-11 and 14 under Section 112 first paragraph and rejected Claims 12-19 under Section 112 second paragraph.

Turning first to Claims 6-11 and 14, the Examiner rejected these claims because she believed that they contained subject matter that was not described in the Specification. In particular, the Examiner objected to the use of the term "about" when referring to 5 cm. of water.

With this Response, the Applicant has amended paragraph 0123 of the Specification to now recite, "about" 5 cm. of water. This change to the Specification is not believed to introduce new matter, since this phrase "about 5 cm. of water" appeared in the originally-filed Claim 6 of the application. As the claims of the application constitute part of the disclosure of

the invention, the Applicant submits that this change is fully supported by the application as filed.

The Examiner objected also to Claim 7-14 because she believed that the ratio of the outer tube diameter to inspiratory tube inner diameter was actually the ratio of the means outer tube diameter to the mean inner diameter of the expiratory tube.

With this Response, the Applicant has amended Claims 7-14 to insert the term "mean", as requested by the Examiner. In this regard, the Applicant submits that this change does not limit the scope of the claims, but rather broadens it, as through the use of the term "mean" the Applicant is relating to the average outer diameter of the pleats.

The Examiner next rejected Claims 12-19 under Section 112. In particular, the Examiner believed that the Specification related to how the tubes are manufactured, as it is believed that terms such as "peak points" and "nadir points" were used in the Specification to primarily describe the mold by which the tube was manufactured.

In particular, the Examiner believed that it was unclear as to whether the finished device or the method of its manufacture was being claimed. She also questioned whether the description of the legs and angles in the originally-filed Specification supported the claims relating to the legs and angles of the finished device.

With this Response, the Applicant has amended the Specification at paragraphs 0111-0116 to clarify this issue that the finished device is being claimed, and that support for same does exist in the originally filed specification.

In this regard, it should be noted that the legs and angles were described primarily with reference to the mold that is used to construct the tube. However, as the extrusion/blow molding technique that is described in the Specification results, as do all extrusion/blow

molding techniques, in a finished product that takes on the "negative" of the shape of the mold in which it is made, the Applicant believes that the description of the mold does provide a description for the finished product. In addition to this inference, the original Specification does refer to the shape of the finished tube as corresponding to that of a mold.

For example, paragraph 0112, as originally-filed states that "when viewing the mold blocks 150, it is important to remember that the mold blocks engaged the exterior surface of the tube. As such, the point that appears to be a nadir point of the mold block (e.g. point 234 of Fig. 7) is actually a peak point 224 as point 224 will define the shape of a peak point of the finished expiratory tube."

To clarify this matter, the Applicant has amended the Specification, so that it now more clearly recites the various features of the mold block, and their relation to the finished tube. As such, the Applicant submits that the Examiner's rejections under Section 112 are now rendered moot.

III. Rejections Under 35 U.S.C. Section 103

A. The Rejection

In the Official Action, the Examiner rejected all of the claims currently in the case under 35 U.S.C. Section 103. To support this rejection, she cited the Clawson and Weigl Published PCT Application WO85/05277 as a primary reference. For various claims, Clawson was combined with Leagre, U.S. Patent No. 5,404,873; Rosenkoetter et al., U.S. Patent No. 5,894,839; Nowacki et al., U.S. Patent No. 4,621,634 and/or Fukunaga, U.S. Patent No. 4,265,235.

For the reasons set forth below, the Applicants submit that the claims, as presented in

this Response, patentably distinguish the Applicants' invention over the art of record.

Prior to discussing the individual rejections and the individual claims, it is believed by Applicants to be worthwhile to first discuss the differences between unilimb breathing circuits that are constructed of corrugated tubing and have a fixed rest length; and unilimb breathing circuits that have a plurality of intermediate rest lengths, (i.e. have a variable rest length) and are constructed of pleated tubing. The differences between the characteristics of a fixed rest length unilimb breathing circuit comprised of corrugated tubing, and a variable rest length unilimb breathing circuit constructed of pleated tubing are highly significant to the manner in which the breathing circuits are designed, and hence highly significant to the patentability of the present invention.

B. A Comparison of Unilimb Fixed Rest Length Breathing Circuits Comprised of Corrugated Tubing and Variable Rest Length Breathing Circuits Comprised of Pleated Tubing.

Unilimb breathing circuits that are constructed of corrugated tubing are shown in each of the Leagre '873 patent, the Rosenkoetter '839 patent, the Fukunagas '235 patent and the Sikora '746 patent. Nowacki is somewhat of a hybrid that employs an outer corrugated tubing, and a non-corrugated (and non-pleated), smooth walled flexible inner tube, in a non-rebreathing type circuit.

Unilimb breathing circuits that are constructed out of pleated tubing are shown in the Clawson '277 application, and Fukunaga et al., Published Patent Application 2003/0075176.

Prior to the instant invention, King Systems Corporation, the Assignee of the present

invention, manufactured corrugated breathing circuits similar to the ones shown in the Leagre '873 and Fukunaga '872 patents. Prior to the present invention, King Systems also produced pleated tubing that it sold under its ULTRAFLEX® brand. However, neither this ULTRAFLEX® brand pleated tubing, nor any other pleated tubing was ever employed by Applicants in a unilimb type breathing circuit that includes an inspiratory and an expiratory passageway, such as is disclosed in many of the references described above.

At first blush, it would seem to be easy to substitute pleated tubing, such as the ULTRAFLEX® brand tubing for the corrugated tubing used in either of the Fukunaga or Leagre patents to create a unilimb breathing circuit that had a variable rest length and was comprised of pleated tubing. Essentially, this substitution of pleated for corrugated tubing was disclosed in the Clawson reference that employs a pair of pleated tubes to form a unilimb circuit.

Notwithstanding the apparent ease of substituting pleated tubes for corrugated tubes in a unilimb circuit, the Applicants found that which seemed simple in concept was quite difficult in practice. The Applicants found that the characteristics of pleated tubing and adjustable length breathing circuits made it very difficult to design a breathing circuit that employed pleated tubing (which gave the circuit its variable rest length) that was safe and efficacious. Significant engineering and inventive efforts were required to create a safe and efficacious pleated tube, variable rest length circuit due to the radically different characteristics of a pleated tube when compared to a corrugated tube, and the difficulty of engineering a circuit that would be safe and efficacious over a wide range of lengths, which is vastly different environment than the generally fixed rest length nature of a unilimb circuit comprised of corrugated tubing.

The Applicants submit that although one can learn from Clawson and Weigl that one could, *conceptually* employ pleated tubes in a unilimb circuit, one could not learn from Clawson and Weigl how to make a safe and efficacious pleated tube unilimb breathing circuit, since nothing in Clawson and Weigl discloses those features claimed in Applicants' invention, that enable the device to be made in a safe and efficacious manner.

In this regard, the features recited in the Applicants' claims relate to such things as the relative sizing, the lengths of the inspiratory and expiratory tubes, the relative diameters of the inspiratory and expiratory tubes, and the offset nature of the patient end of the inspiratory tube. By contrast, nothing is stated in the Specification of the Clawson and Weigl reference about the relative diameters of the inspiratory and expiratory tubes. The only suggestion of relative diameters is the suggestion given by looking at the drawings, that show relative diameters that are out of the range claimed by the Applicants. Additionally, the patient end connector of the inspiratory tube of the Clawson Weigl reference is centered within the expiratory tube, teaching away from the offset connector claimed by the Applicants.

With respect to the relative lengths, Clawson and Weigl state that "there is no need to match or cut [the inspiratory and expiratory tubes]... to matching lengths". This, completely contradicts and teaches away from the Applicants' recitations relating to the inspiratory tube being longer than the expiratory tube.

One fact that supports the Applicants' contention of the difficulty of designing a safe and efficacious variable rest length pleated tube circuit is the fact that the Clawson Weigl reference was first published in 1985, over 20 years ago. In this 20 year period, no one other than King Systems Corporation has apparently been able to bring to market a pleated circuit variable rest length unilimb circuit. The absence of any other variable rest length, pleated tube

containing unilimb circuits is particularly indicative of the Applicants' inventiveness because the Applicants understand that others within the industry have sought to produce such a pleated tube unilimb variable rest length breathing circuit, to achieve those benefits provided by such a circuit.

Further, the differences between the behavior of pleated tubing and corrugated tubing, and the differences between the variable rest length breathing circuit, and a fixed rest length breathing circuit would not have enabled one to combine the teachings of references such as the Leagre, Rosenketter, Nowacki and Fukunaga, that relate to fixed length corrugated tubing circuits with Clawson and Weigl to achieve the Applicants' invention.

One significant difference between corrugated tubing and pleated tubing, when incorporated into a unilimb circuit, is that the diameter of corrugated tubing remains generally constant in use. One reason that corrugated tubing retains a constant diameter is that in most situations, it remains at its fixed rest length. However, even when stretched or compressed (both of which tend to be transient events) the diameter does not change significantly.

By contrast, the diameter of pleated tubing changes significantly. When pleated tubing is expanded, its outer diameter tends to be smaller, and its inner diameter tends to be larger. By contrast, when pleated tubing is compressed, its outer diameter tends to grow larger and its inner diameter tends to grow smaller.

The impact of this changed diameter in a unilimb circuit, such as is shown in the drawings of the Applicants' device, is that the "area" of the expiratory passageway tends to be significantly smaller when the expiratory and inspiratory tubes are compressed, and larger when the expiratory and inspiratory tubes are in their expanded position.

The area between the exterior of the inspiratory tube and the interior of the expiratory

tube is highly important to the functioning of the device, as this area defines the expiratory passageway through which expired air is conducted from the patient back to the anesthesia machine. In order for a device to be considered safe and efficacious, this passageway must be configured so that it will achieve a flow resistance of less than about 5 cm. of water at 60 liters per minute of flow.

A low flow resistance is normally achieved by making the area of the expiratory passageway large enough and unimpeded enough so that flow resistance is maintained at an acceptably low level. Achieving a low flow resistance is often not that difficult when the device is in its fully expanded position, due to the relatively smaller outer diameter of the inspiratory tube and relatively greater inner diameter of the expiratory tube (when compared to the tubes being in their compressed position). However, achieving a suitable flow resistance is more difficult when the tube is in its compressed position, where the inner diameter of the expiratory tube is relatively smaller and the outer diameter of the inspiratory tube is relatively greater.

Although this problem would seem to be easily surmountable by greatly enlarging the diameter of the expiratory tube relative to the inspiratory tube, this "simple solution" does not work. The reason it does not work is that if the inner diameter of the expiratory tube is too much greater than the outer diameter of the inspiratory tube (such as at the ratio shown in Clawson and Weigl's drawings), flow resistance can actually be increased. The reason the flow resistance can increase is that if the breathing circuit is moved from its relatively more expanded position to a relatively more recompressed position, the significant size difference between the diameters of the inspiratory tube and the expiratory tube will often cause the inspiratory tube to adopt a snake-like configuration within the expiratory tube. This snake-like

configuration can actually increase flow resistance to unacceptable levels.

This "snaking" is not a problem in corrugated tubes, since the length of a corrugated tube is chosen to mate with its corresponding expiratory tube at the pre-determined rest length of the two tubes, since that is the condition in which the device is usually employed. Because of the spring-like nature of a corrugated tube, the corrugated tube cannot be maintained in a compressed position without extraordinary measures. Since the corrugated tube cannot normally be kept in a compressed position without extraordinary measures, there is little chance of "inspiratory tube snaking" occurring in a corrugated breathing circuit.

As such, the issue of sizing the relative diameters of a inspiratory tube to an expiratory tube in a unilimb circuit that is present in a pleated breathing circuit is much less complicated in a corrugated breathing circuit. Through significant engineering acumen and inventive efforts, the Applicants' invention discloses and claims a range of inspiratory and expiratory tube diameters that will both provide significant area within the expiratory passageway, without resulting in undue snaking of an inspiratory tube when the tube is compressed, to thereby create a safe and efficacious circuit.

Another impact of the variability of the diameters of the inspiratory and expiratory tubes relates to the manner in which one configures the patient end coupling of the inspiratory tube.

The "normal" way to couple the inspiratory or inner tube to the patient coupling is to center the inspiratory tube coupling within the expiratory tube, such as is shown in all of the references cited by the Examiner, with the exception of Nowacki.[1]

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[1] As will be discussed in more detail below, an issue of such interference is not present in Nowacki due to the manner in which the Nowacki device works, and the nature of the inspiratory tubing used with Nowacki

Contrary to logic and all prior art, the Applicants have found that flow resistance is reduced when the inspiratory coupling is actually offset from center of the inspiratory tube. Obviously, Clawson and Weigl did not grasp this fact, as they have chosen to center their patient end coupling of the inspiratory tube. Leagre, Fukunaga and the other corrugated tube references do not face this problem, since the diameters of their inspiratory and expiratory tubes would not vary, or if they do vary, varied insignificantly.

Another significant difference between a variable rest length pleated tube of the present invention, and a corrugated tube containing a fixed length unilimb breathing circuit is that the rest length, and hence the length at which the circuit is used in a variable rest length circuit varies widely between a compressed and expanded position. In the Applicants' invention, the length of the tube in its expanded position will often be between 300 and 400 percent (three or four times greater) than the length of the circuit end tubes in its compressed position.

By contrast, a corrugated circuit has a fixed rest length. Corrugated tube operates somewhat like a spring when either compressed or expanded. That is, when one attempts to compress a corrugated tube, the tubes will be under stress, similar to a compressed spring. This compression causes the tube to want to expand back to its normal rest length position. Similarly, when expanded, a corrugated tube will be under stress of the type that will cause the corrugated tube to work against the forces of expansion, to cause the tube to contract back to its rest position. Additionally, a corrugated tube is not capable of being expanded to the extent to which, for example, the Applicants' tube can be expanded in length. Rather, a corrugated tube of the type the Applicants employ in their products, will generally only increase its length by about 20 percent or so from its rest length even when pulled with significant force.

In practice, these characteristics of a corrugated tube mean that a corrugated tube is almost always used at a length that is equal to approximately the rest length of the inspiratory and expiratory tubes. If, for example, a corrugated inspiratory tube is expanded, the force of the tube counteracting the expansion tends to either pull the patient's face mask or intubation tube off of the patient, or may pull the anesthesia machine (if on wheels) toward the patient. Similarly, a corrugated tube can only be maintained in its compressed position through the use of an extraordinary clamping system of the type that is highly unlikely to be employed by a user, as it would likely serve no purpose.

As such, although it is important to size the relative lengths of a pleated inspiratory and expiratory tubes carefully to ensure that the breathing circuit is safe and efficacious over a wide variety of lengths, such concerns are not as important when using corrugated tubes.

The Applicants have found that several complications arise in this sizing. One complication relates to the issue of sizing the inspiratory and expiratory tubes relative to each other, so that one can maximize the length to which the combined circuit can expand. One factor that complicates this ability to size the inspiratory and expiratory tubes to be able to maximize the length, is that the different diameters of the inspiratory and expiratory tubes might cause the two tubes to have very different lengths to which they can expand.

This difference in potential expansion length may result from the fact that the difference in lengths of the "legs" of the pleats of the two tubes differ due to the different diameters of the tubes. If the respective lengths of the legs of the two tubes are not sized appropriately, it is possible that one of the tubes would be capable of expanding far beyond the ability of the other tube to expand.

In addition to these differences in expansion being inefficient due to the fact that they

would not take full advantage of the tube's ability to expand, possible safety issues could arise. For example, if the expiratory tube were capable of expanding to a much greater length than the inspiratory tube, it is possible that an attempt by the user to expand the expiratory tube to its full length would create undue stress between the inspiratory tube and its coupling to its distal or proximal coupling member, thereby causing the inspiratory tube to separate from the coupling member. If this disengagement occurs at the machine end (proximal end) of the tube, a significant efficacy issue may result due to the creation of too large of a dead space area.

Although the maker of a corrugated tube must also contend with the issue of preventing a disconnect, this concern is not nearly as significant.

As the Examiner states, Rosenkoetter teaches only that the lengths of the tubes may be standard or selected tubing length, such as those typically used for anesthesia or respiratory breathing circuits. As such, Rosenkoetter teaches that length is not that important. This is not surprising as Rosenkoetter employed a corrugated circuit, and was therefore not faced with the problem of matching the lengths of tubes in a pleated circuit over a wide range of useable (rest length) positions. As stated above, Clawson and Weigl state that there is no need to match or cut the inner and outer tubes to matching length, in their pleated circuit, thus failing to appreciate the problem.

Importantly, employing Rosenkoetter's suggestion of adopting tubing that is of the length such as those typically used for anesthesia or respiratory breathing circuits would not work with the Applicants' invention, since none of the prior known breathing circuits, to the Applicants' knowledge, employ pleated tubing. As stated above, Clawson and Weigl is no help whatsoever, as Clawson and Weigl's statement of no need to match the inner and outer tubes or cut them to matching lengths, teaches away from the Applicants' invention. Nor does

the Fukunaga patent application provide any guidance with respect to length.

In summary, the differences between a unilimb breathing circuit having a fixed length, and comprised of corrugated tubing; and a unilimb breathing circuit having a variable rest length and comprised of pleated tubing are sufficiently great, so that one cannot apply the teachings of a corrugated fixed rest length circuit to a variable rest length pleated circuit and expect the pleated circuit to operate in a safe and efficacious manner.

IV. Particularized Discussion of the Claims and the Rejections

The Examiner first rejected Claims 1-3 and 12-15 under 35 U.S.C. Section 103 as being unpatentable over Clawson, in view of Leagre and Rosenkoetter.

Claim 1 includes a recitation of a unilimb breathing circuit including an expiratory tube and a pleated inspiratory tube; and that both include a plurality of intermediate rest positions, wherein the tubes are capable of maintaining these plurality of rest lengths. Claim 1 also recites that the length of the inspiratory tube is greater than the length of the expiratory tube. Claims 2 and 3 recite the range of lengths by which the inspiratory tube should exceed the length of the expiratory tube.

These features are not disclosed or suggested by the references combined by the Examiner.

Clawson is the only reference that relates to a pleated tube variable rest length circuit. Clawson clearly does not understand the problem involved, or the Applicants' invention, as he teaches away from the Applicants' invention by stating that there is no need to match or cut the inner and outer tubes to a matching length.

Leagre and Rosenkoetter are inappropriate to combine with Clawson, since the

environment in which they operate (a fixed rest length corrugated tube) is very different than the environment of a variable rest length pleated tube circuit claimed by the Applicants. Additionally, other significant differences exist.

The Examiner is correct, as the Leagre reference discloses that the inspiratory tube should be longer than the expiratory tube. However, the reasons for this increased length are very different than the present invention. It should be noted that unlike the present invention, Leagre's inspiratory tube is designed to **not** be fixedly coupled to the patient end connector. (This is also the case with the Fukunaga '235 patent).

The Leagre device employs a "floating coupling" between the distal end of the inspiratory tube and the patient end coupling, to reduce the potential for disconnect that would occur if the expiratory tube is stretched. As such, the inspiratory tube does not expand with or contract with the expiratory tube. Rather, the expiratory tube normally expands independently of the inspiratory tube. Leagre employed a longer inspiratory tube length not to permit the inspiratory tube to expand with the expiratory tube, but rather to maintain the inspiratory tube closely adjacent to the patient end of the breathing circuit to thereby minimize dead space.

By contrast, the Applicants' invention couples both the proximal and distal end of the inspiratory tube to their respective machine end and patient end couplings. As such, it would not be obvious to combine Leagre who employs neither a pleated circuit nor a coupled inspiratory tube, to Clawson to achieve the Applicants' invention.

Rosenkoetter provides little other assistance.

Like Leagre, Rosenkoetter's tube is a fixed rest length corrugated tubing circuit, rather than the variable rest length pleated tubing circuit of the present invention. Rosenkoetter's statement that "the tubes may be any standard or selected tubing length"

demonstrates his lack of appreciation for the appropriate length sizing that exists in the variable rest length pleated tube circuit such as the Applicants. Additionally, as discussed above, there existed no standard or selected tubing length for Applicants to employ with a pleated tube circuit, as no pleated tube unilimb circuits existed on the market prior to Applicants' device, from which Applicants could have chosen.

As such, one could not have combined the three references to achieve the Applicants' invention, as none suggest the use of the longer inspiratory tube in a pleated variable rest length circuit.

With respect to Claims 2 and 3, it is believed that the ranges set forth therein would be inappropriate for use with a corrugated tubing circuit. In the Leagre device, the purpose of making the inspiratory tube slightly longer than the expiratory tube, is to cause the inspiratory tube to fit tightly up against the patient end of the expiratory tube coupling. As such, the undersigned understands that the commercial circuit made under the teachings of the Leagre Patent (the King F-1 circuit) has an inspiratory tube that is only about 0.5 inches longer than the expiratory tube. If for example, the inspiratory tube were made significantly longer, such as the three to five inches, and most likely the one to seven inches disclosed in Claims 2 and 3, the additional length would likely cause the inspiratory tube to "snake" within the expiratory tube, thus adversely affecting the flow resistance of the expiratory passageway of the device.

Applicants' Claim 12 does include a recitation similar to Claim 1 of the inspiratory being longer than the expiratory tube. However, Claim 12 includes recitations that both the inner and outer tubes include pleats that contain a first leg and a second leg, and that the legs are disposed at a "second angle" when the pleats are in their expanded rest position.

Clawson discloses nothing about the relative angles of the inspiratory and expiratory

tubes in a unilimb circuit. As stated above, the statement about there being no need to match the length of the tubes or cut them to a matching length, argues persuasively that he had no conception or appreciation of the problems of enabling his inspiratory and expiratory tubes to match the lengths to which they could expand.

Leagre and Rosenkoetter, dealing with corrugated tubing, and fixed length circuits were dealing with tubing, that did not necessarily have differences in angles, because they had no pleats. There is nothing in either reference to suggest that these pleatless tubes could be modified to achieve the Applicants' invention. Although the Examiner asserts that it would be obvious to one skilled in the art to make the second angle of the inner pleats greater than the second angle of outer pleats to achieve a greater length, the Applicants' respectfully submits that it would *not* be obvious to do so from the teachings of Leagre or Rosenkoetter, as they were not dealing with pleats with angles.

Further, and more importantly, neither Leagre nor Rosenkoetter were faced with the problem of designing an inspiratory tube that was capable of matching with the length of an expiratory tube, over a very wide range of respective rest lengths. As such, they would have no need to suggest the Applicants' claimed solution, as they did not face the problem faced by the Applicants. As such, the Applicants' submit that its Claim 12 patentably distinguishes the Applicants' invention from the art of record.

With respect to Claim 13 and 15, there is nothing in Leagre or Rosenkoetter that suggests employing a particular size ratio of an outer diameter of an inner tube to an inner diameter of an outer tube in a unilimb circuit having a variable rest length and pleated tubes to minimize flow resistance, while facilitating linear compressability and expandability.

Nor is Clawson of any help since Clawson's text does not mention anything about the

ratio of the outer diameter of the inspiratory tube 108 to the inner diameter of the expiratory tube 110.

The Examiner then rejected Claims 4 and 17 as being unpatentable over Clawson in view of Leagre and Rosenkoetter as applied to Claim 1, and further a review of Nowacki.

Applicants' Claim 4 recites the presence of a re-breathing type unilimb breathing circuit having a pleated expiratory tube and a pleated inspiratory tube, with each tube having a plurality of intermediate rest positions. Claim 4 goes on to further recite the presence of a distal end coupling member that includes an axis-containing terminus for receiving the inspiratory tube, with the axis of the terminus being radially offset from the axis of the distal end coupling member.

As discussed above, each of the Clawson, Leagre and Rosenkoetter references use a terminus axis that is radially centered, rather than offset from the axis of the distal coupling member.

Nor would it be obvious to combine Nowaki into this mix to achieve the Applicants' invention.

The Nowacki '634 patent discloses a Bain circuit. It is first important to note that a Bain circuit is not a rebreathing circuit. In a rebreathing circuit, such as the Applicants', exhaled gas is directed back to an anesthesia machine, where it is mixed with a fresh gas, oxygen, and stripped of its carbon dioxide, and re-circulated back to the patient. By contrast, a non-breathing, Bain circuit does not re-circulate the patient's expired gas. Because the gas is not re-circulated, the inspiratory tube is almost always smaller, and feeds gas under pressure to the patient. A smaller inspiratory tube of the type shown by Nowacki will not cause as much resistance to flow, in the expiratory conduit as is typically encountered with a larger inner tube

or re-breathing circuit.

The benefit obtained by the Applicants' offset terminus is to reduce flow resistance in the expiratory pathway at the patient end of the circuit. Reduction of flow resistance does not appear to have been a motivating factor for Nowacki's offset tube. Rather, it appears that Nowacki's primary motivator for making his inner tube offset at the patient end was either to provide a crank effect that facilitates assembly of the tapered exhaust fitting to thereby ensure a tighter connection (as recited at Col. 1, lines 55-58) or to provide an inexpensive and secure anesthesia tubing connection, that is made more secure than those in the prior art due to the interlocking construction, see Col. 4, lines 66-69, and Col. 5, lines 1-2 of the Nowacki '634 patent.

Nowhere in Nowacki is there any disclosure or suggestion of using a radially offset connector for the purpose of reducing flow resistance, or using a radially offset connector in a rebreathing circuit. Most likely, there is no disclosure or suggestion in Nowacki of using a radially offset terminus to decrease flow resistance, due to the fact that flow resistance is not a major issue when using the relatively smaller diameter inspiratory tube typically used at non-rebreathing type Bain circuits.

Nor is it necessarily apparent that flow resistance will be unduly compromised by the use of a non-offset inner tube in a rebreathing circuit of the prior art. In this regard, the Examiner's attention is directed to the other references cited by the Examiner, all of which use a centered (rather than offset) patient end connector for the inspiratory tube.

Importantly, one would not look to Nowacki's use of an offset reference to achieve the Applicants' result, since Nowacki's device operates in an environment totally different than the environment in which the Applicants' device operates.

As such, the references cited by the Examiner cannot be combined to either disclose or suggest the Applicants' claimed invention.

With respect to Claim 17, it should be allowed based if nothing else, on its dependency from Claims 12-15 discussed above, that when combined with the additional features in Claim 17, give Claim 17 strong basis for patentability independent of Claim 17's dependence from other claims.

The Examiner next rejected Claims 5-11, 13-16, 18, and 19 as being unpatentable over Clawson, Leagre, Rosenkoetter and Fukunaga.

Applicants' Claim 5 relates to a unilimb breathing circuit having a pleated expiratory tube and pleated inspiratory tube. Each of the inspiratory and expiratory tubes include an outer diameter, and an inner diameter. Claim 5 goes on to recite that "the ratio of the outer diameter of the inspiratory tube to the inner diameter of the expiratory tube is sized to minimize flow resistance there between while facilitating generally linear compressability and expandability of the inspiratory and expiratory tubes".

The Applicants' submit that the references cited by the Examiner could not be combined to achieve the Applicants' invention.

As discussed above, the Fukunaga '235 patent discloses a device that has significant similarities to the Leagre device, as both relate to a corrugated tube, fixed rest length, unilimb circuits, with each containing an inspiratory tube having a patient end that is not fixedly coupled to the patient end coupling.

Fukunaga may mention the inspiratory and expiratory tube having a difference in diameters such that a sufficient volume of expiratory gas may pass between the outer wall of the inner tube and the inner tube of the outer tube. Nonetheless, Fukunaga's disclosure of this

intended result to be achieved cannot render the Applicants' invention obvious, since nowhere does Fukunaga disclose or suggest how to achieve such flow resistance in a unilimb breathing circuit having pleated tubes that have a variable rest length. As discussed above, significant inventive skill was necessary to create the Applicants' invention. Nor would it have been obvious to combine Fukunaga with the remainder of the references, or even a pleated tube reference such as Clawson, where Clawson does not disclose or suggest anything about the relative sizing of the inspiratory and expiratory tubes.

As such, only through a hindsight analysis could one have achieved a device that is recited in Applicants' claims, and in particular, Applicants' Claim 5.

Further, there is nothing in Fukunaga or any of the other references that would have suggested using any of the range of sizes suggested in Claims 7-11, or for that matter, Claims 18 and 19, through their various dependencies.

V. Conclusion

For the foregoing reasons, the Applicants submit that none of the references, either singly or combined, could have either disclosed or suggested the Applicants' invention. Rather, the Applicants submit that their claims patentably distinguish the Applicants' invention from the art of record. Re-examination and re-consideration of the claims, culminating in the allowance thereof, is respectfully requested.

Applicant requests that this Response be considered a request for an extension of time for a time appropriate for the response to be timely filed. Applicant requests that any required

fees needed beyond those submitted with this Response be charged to the account of **E. Victor Indiano, Deposit Account Number 50-1590.**

Respectfully submitted,

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